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From: Marjo Jrvinen [marjoj@sci.fi]
Sent: Friday, May 28, 1999 9:33 AM
To: fdadockets@test.oc.fda.gov
Subject: Fragrance petition, docket No. 99P-1340/CP1

Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Re: 99P-1340/CP 1
Petition to Have "Eternity eau de parfum" Misbranded

Dear Sir or Madam:

In May, 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's "Eternity eau de parfum" declared misbranded. I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 specifically states:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: "Warning--The safety of this product has not been determined."

As the petition shows, "Eternity" contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as "Eternity" so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may effect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses.

Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, care givers and teachers. When I am exposed to fragrance products, such as "Eternity," I experience:

- rhinitis
- breathing problems - asthma-like symptoms and coughing
- I have lost my voice
- I have vomitted
- strong headaches
- dizziness
- I stopped using fragranced products in March 1991
- I can no more work outside home, visit my friends nor invite guests
- I have to live in a totally fragrance-free environment

99P-1340

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Because of this, toxic chemicals in fragrances have already ruined countless lives.

Thank You.

Marjo Jarvinen

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FIN-02340 ESPOO,
Finland

P.S. On February 4, 1999 I wrote a letter (posted via regular airmail) for the attention of Mr. Charles Hayes, CFSAN, Washington, DC, I paste it here:

Mr. Charles Haynes
CFSAN
HFS-105,
200 C Street, S.W.,
WASHINGTON, DC 20204
U S A Espoo, February 4, 1999

Re: Health effects of fragranced products - comments to be attached to the "Stakeholder's " meeting

Dear Mr. Haynes,

I am a 48 year old woman, married and have two sons.
Education: Academic Secretary (1975) and Bachelor of Economic Sciences (1975), graduated at Helsinki School of Economics and Business Administration
I am atopic and extremely sensitive to all fragranced products.

My allergy to fragrances was tested in 1991 and the test result was positive.

Symptoms:

- the first symptoms were rhinitis and itching and sore eyes (rhinitis was caused by perfumes and aftershaves and strong scents, did they cause my eye-problems, that I cannot say for sure, I used at my work for 8,5 years daily all the time carbonless copy paper and it caused me rhinitis, too.)
- then I started to have breathing problems, asthma-like symptoms
- I have lost my voice. E.g. I was seeing my dermatologist and there was a young and scented girl before me, when I went after her to the reception room, I had lost my voice.
- I have vomitted when exposed to strong scents
- at work I had very often headaches, but I do not know what caused them (May 28, 1999: Yes I do get strong headaches from perfumes, e.g. last Valentine's Day my neighbour (smelled perfume) hugged me quickly and we talked about 5 minutes, she was standing outside, but I got headache which worsened towards the evening - a Valentine's Day gift!)
- I have had four times during ca. 10 years balance problems, when walking I suddenly noticed that I was falling to my left side, this has always happened very quickly and suddenly, as if I were drunken. The last time it happened when I came out of a bus coming home from the

computer training (more of it below). I do not have problem with blood pressure.

How quickly do I react:

On exposure of perfumes or aftershaves or other strongly scented products my reaction is immediate. If I am able to leave away immediately I am feeling OK but if I have to breathe the scent for e.g. 15 - 30 minutes I will be coughing for the rest of the day and have to use medication.

I do grocery shopping nearly daily in the middle of the day. I do smell that the inside air in the grocery store is not fresh and I do my shopping very quickly. If I am lucky not to be forced to stand near a scented person I am well when coming home, but sometimes I am not so lucky and get asthma-like symptoms at the store. Then my only thought is to get out of there as quickly as possible and many times I have been close to vomiting when getting out. The rest of the day is then spoiled. I do not visit my neighbours or friends. When they open their front door the inside air smells so scented that I do not take the risk.

Once a friend of my son was taking a shower in our bathroom. When he opened the bathroom door I ran quickly to kitchen and closed the door. He had brought his own shampoo with him and it did scent awful. I went for a walk for one hour, my family aired our house during that time and my sons washed the shower cubicle.

The boy in question started to use a fragrance-free shampoo! This happened during my computer training course. Now I am much more careful.

Impact on my social life:

I cannot work outside home, I cannot go to theater or movies or restaurants, I prefer not to use a bus and especially not when it is rush-hour. I cannot travel by airplane or train etc. I cannot invite guests and I cannot visit my friends.

I keep contact to my friends via telephone and e-mail.

I can meet people outdoors but if they use perfume or aftershave or other strong scent or a scented laundry detergent, e.g. OMO, I cannot walk or sit near them.

I jog and walk ca. 3 to 4 times a week, 45 minutes jogging or over 60 minutes walking, especially from April to end November, when there is not snow. I do not have any breathing problems, except when I meet there a strongly scented person, then I just stop breathing for a while, there is a wake of scent of at least 20 meters after that person.

I do also bodybuilding and weight lifting, but only at home, 3 to 4 times a week, 45 to 60 minutes per training.

Medication:

The ONLY thing that helps me, is the AVOIDANCE of perfumes, aftershaves, laundry and cleaning detergents and other fragranced products.

Now when I am at home, I do not need any medication daily.

If I get symptoms, e.g. when shopping, I take:

- one pill Zyrtec 10 mg (Cetirizini Dihydrochloridum) by UCB Pharma Oy, Finland

- one capsule of Lomudal 20 mg, (Natrii cromoglicas), by Fisons Plc., England, it has to be inhaled using inhalator. I may use one capsule 4 to 8 times per day.

If that does not help, I take Atarax 10 mg (Hydroxyzini Hydrochloridum), by UCB S.A., Belgium - 1 to 2 pills 1 to 3 times a day.

Zyrtec helps to rhinitis. Lomudal may help to asthma-like symptoms

together with Zyrtec.

Atarax normally helps me to be able to sleep. Now, when I am at home, I have not needed Atarax.

- When I was working at a bank, at documentary credits, I used Atarax 1 to 2 pills a day, 5 days a week for ca. 7 years to be able to work.
- For my eyes I used Lomudal 40 mg/ml eye-drops, without preservative, by Fisons Plc., England
- For allergic inflammation of the eye the only medication that helped was: Terra-Cortril-P, a cortisone ointment by Pfizer Oy, Espoo, Finland, (Pfizer Inc. Trademark).

At the computer training course beg. February 1997 I used:

- Lomudal eye-drops and Terra-Cortril-P cortisone ointment.
- I did not have eye-problems during the course.
- For my allergic rhinitis and asthma-like reactions to fragranced products I used:
 - Atarax and Zyrtec
 - Inhaled Lomudal 20 mg (Natrii cromoglicas)
 - Lomudal Nasal nose-spray
 - Pulmicort 200 microgram per dose, first 4 doses twice a day for ca. 3 weeks and later on 2 doses twice a day. I used it for 2,5 months daily. (A product of ASTRA)
 - Bricanyl 0,25 mg per dose, 1 dose 4 times a day. As I do not have asthma, this medication does not help me.

Except Bricanyl, I used all the other medication up to maximum but they did not help me, only when our class stopped using perfumes, aftershaves, scented deodorants, hair sprays,

body lotions etc., I could go on with the training.

But, the result was that now I am hypersensitive to all fragranced products. Actually I could say that the medication did not help me it just allowed me to be among people and to be exposed to scents with disastrous consequences to me.

Short historical review:

Due to my atopy I have always been very sensitive to laundry detergents, beauty products and household detergents.

When I was a teenager I tried to use sprayed deodorants but I have got eczema from them and had to use a very mild roll-on deodorant (MUM), I did not like to be different!

In my youth people did not use much perfumes and scented products, only when they went out for a party.

I have got my first eau de cologne at the age of 21.

At the age of ca. 20 I got skin irritation (itching) from a cloth my mother had washed using a laundry detergent called OMO. I always tried to find the most sensitive product and tested it with myself.

I was ca. 30 years when I have got a bottle of Revlon's Charlie. I immediately sprayed it around my neck in the evening and the next morning my neck was full of tiny red spots as if it had been pricked by a needle and it was itching. I gave 'Charlie' to my co-worker but regretted it soon because I did not 'like' Charlie's scent.

The only perfume I could use was Shalimar by Guerlane. Once I got as a free of charge sample a small bottle of Nuit Orchid  by Yves Rocher, first it smelled great but very soon I have

got immediate rhinitis after putting it onto my wrists. I stopped using it.

In 1991 after having the results of the allergy test I stopped using even tiny scented products and so did my family.

My husband started to get skin irritation from aftershaves, it did all easier.

But if one has to work, travel by bus, go shopping, take part in meeting etc., it is impossible to avoid perfumes, aftershaves and other

fragranced products. I had to use antihistamine (Atarax and Zyrtec) to be able to work.

I had difficulty in breathing near scented people; perfumes and aftershaves that had earlier smelled great suddenly started to smell very bad. Many times I thought 'how can she/he use such a scent, it smells terribly bad'.

At the beginning of 1994 I quitted my job, I simply did not like to live my life eating Atarax and coughing and coughing. I stopped using antihistamines and was feeling very well at home. I have got symptoms during strong birch pollution and if I went shopping clothes. I thought that my rhinitis and coughing were due to dust mites in those shops. I could not visit our next-door neighbour, I just could not breathe there; once I was there for 20 minutes and vomitted when coming out. I thought that I was 'allergic' to their dog. My neighbour is a cosmetologist and very strongly scented and accordingly their inside air is full of strong scents, this I learned later on.

At the end of February 1997 I started a computer training course. We were 15 persons in a classroom and the only way to get fresh air, was to open a window. When we introduced ourselves, I said that I am allergic to perfumes and aftershaves and asked the other students not to use them, if possible. The first day was ca. 6 hours long. When I came home I was feeling so ill, I was coughing and coughing, I felt that my respiratory passages were full of dust and scents.

I washed myself, my nose, my mouth, went to sauna for 4 times and took a pill of Atarax but nothing helped. I could not sleep because I could not breathe normally and I was coughing all the time. I was terrified, I was crying and I took another pill of Atarax, it was over one o'clock in the night and I had to wake up at 6.30 in the morning. I did fell asleep. I went to see a doctor and he gave me asthma-medication. It did not help, I called him and asked for allergy medication, too (inhaled Lomudal). Nothing helped. I thought I was going to have asthma. I phoned to our Allergy and Asthma Association, I thought that there will be something that could help me. Nothing.

At the end of the first week I told that I have to stop the training course. Those in head suggested that they will talk to my class and ask them, whether they could stop using scented products for 2,5 months so that I could take part in the training. They promised and, I believe, did their best but they were not unscented. However, this helped me a lot. I was daily 4 hours at the training and was allowed to do the homework at home. There were other classes too, and they did use scented products, there were air fresheners in toilettes, I had to travel by bus totally one hour per day.

I had very bad days and I wanted to give up, but I did finish that training. Ever since I have been sitting at home. I can smell everything, even tiny amounts of fragrances, those that 'normal' person does not smell. At home I often forget that I am not a normal person. Now I have a car, so I do not have to use busses. If I go shopping (grocery store), I go there in the middle of the day when there are only a few other people but unfortunately even one strongly scented is enough for me and my day is spoiled, I have to take medication when coming home. During weekends I do not go shopping, there are too many scented people.

When my sons go to school / university, they put on fragrance-free clothes. When they come home they smell, their hair smells and clothes smell. We take the clothes out every day.

Those, which I do not wash regularly, are kept in a wardrobe behind a closed door.

It is difficult to get the scent out of clothes, first I air them, then I wash them, then I air them 2 to 3 days, but there is

still a tiny amount of scent left.

I am very worried of the young people today who use lots of scented products and strongly scented!

Allergy-tests:

Due to urticaria and breathing problems I have been studied at The Helsinki University Central Hospital of Allergy on January 23 to 24, 1988. I did not have asthma. No positive results in prick-test. (Fragrances and perfumes were not studied, just foodstuffs, scale of animals, pollution of trees and heys). Reason to my symptoms was said to be my atopy.

Medication used: Lunerine Mite, Atarax 10 mg and Phenergan.

Ventoline was prescribed for breathing problems. It did not help and I stopped using it.

On February 2, 1988 I was tested in a private laboratory, also a prick-test. Garlic gave positive reaction.

Garlic was not tested in January 1988. My stomach got very ill, if I ate garlic. A couple of years later, I started to have urticaria from tiny amounts of garlic, e.g. in spice-mixtures.

Once again on March 11 to March 13, 1991 I was tested due to urticaria, eczema, red and sore eyes and breathing problems. This was a patch-test and the results were: Clear allergic reaction to epoxy-harz and fragrance-mixture and positive reaction to natural harz and thiomersalate (thiomersal, used as preservative in vaccines and eye-drops). This was made by Allergiatesti Oy, Helsinki, my private dermatologist had sent me there.

She told me that I may not use any scented products including household cleaning detergents.

Those few I still was using I threw away. The only perfume I could use was Guerlain's Shalimar but I stopped using it, too. She also said that I must ask my co-workers not to come to my room scented. In practice this did not work.

The positive reaction to fragrances did not surprise me, I had been testing all my life cosmetics and there were only few I could use, usually I got eczema or irritation and stopped using the product. I was also very careful with laundry detergents, used the most sensitive available. At that time it was very difficult to find fragrance-free products. Deodorant had to be bought from pharmacy as well as skin-care products.

This, however, did not help and I had all the time when working both breathing problems and sore eyes and sometimes urticaria. (This was when garlic, even in tiny amounts like spice-mixtures, started to cause me urticaria, I found it out myself when testing myself!)

Again on December 2, 1992 I was studied at The Helsinki University Hospital of Allergic Diseases.

Prick-test again. Only a small reaction to aureo basidium bullulans.

This test was similar to that made on January 23/24, 1988.

I was working at a bank, at documentary credits department, during September 2, 1985 to February 19, 1994, totally 8,5 years. I used daily and all the time carbonless copy papers at my work, they caused me breathing problems and rhinitis, too. I thought that they were the reason to most of my symptoms. During weekends and on holidays I was feeling well and did not have to take antihistamine medication, at work I had to use antihistamine.

I quitted my work and at the same time stopped using Atarax or other

antihistamines.

Yours Faithfully,

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